

amended. Support for the amendments may be found throughout the specification, including the claims as originally filed. No new matter has been added.

Amendment of claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The amendments to the claims are being made solely to expedite prosecution of the present application and do not, and are not intended to, narrow the claims in any way. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application.

In response to the comments at page 2 of the Office Action relating to the group and species election, Applicant's wish to reiterate that the election of group I (claims 43-64) and SEQ ID NO: 13 as the species in the response to Restriction Requirement dated December 2, 2001 were made **with traverse**. Furthermore, Applicant's distinctly and specifically pointed out the errors in the restriction requirement in conjunction with making the election **with traverse**.

Claims 43, 46, 49 and 51-56 Rejected under 35 U.S.C. §112, first paragraph

Claims 43, 46, 49 and 51-56 were rejected under 35 U.S.C. §112, first paragraph, for reasons of written description. The Action states that:

***Applicants have argued that the specification clearly conveys to one skilled in the art that the applicants were in possession of the claimed genera, however they do not provide any evidence in support of their arguments. Different sections of the specification cited by the applicants do not address the issues of identifying characteristics of the species of the claimed genus and other issues. (Office Action at 2-3)

The rejection is respectfully traversed.

Applicants respectfully disagree with the rejection, however, in an effort to expedite prosecution of the application, claim 43 has been amended. The claim amendments are believed to obviate the rejection.

Applicants further wish to point out that the specification clearly conveys to one skilled in the art that the Applicants were in possession of the claimed genera at the time the application was filed. As required by the interim written description guidelines, the specification provides a

sufficient number of species to support the currently claimed genera. For example, the specification provides the complete coding region for the ENV polypeptide, comprising nucleotides 5620 to 7590 of SEQ ID NO: 3 (see e.g., Figure 3). Figure 4 and Example 9 (at pages 30-34 of the specification) additionally provide the complete sequence of a modified version of the ENV gene isolated from RAJI cells infected with PoEV (SEQ ID NO: 9). The specification further teaches (see e.g., pages 15-16 of the specification) that conservative amino acid replacements may be made while retaining the function of a protein. The Specification also discloses that nucleotide sequences having at least 95% sequence identity to SEQ ID NO: 3 may be isolated by their ability to hybridize with this sequence (see e.g., pages 7-8).

Accordingly, the specification clearly supports that Applicants' were in possession of the claimed invention at the time of filing the Application. In view thereof, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 43, 46, 49 and 51-55 Rejected under 35 U.S.C. §112, first paragraph

Claims 43, 46, 49 and 51-55 were rejected under 35 U.S.C. §112, first paragraph, for reasons of enablement. In particular, the action states that:

***[T]he specification, while being enabling for (i) an isolated polynucleotide disclosed in SEQ ID NO: 1, 2 and 3 wherein the polynucleotides of SEQ ID NO: 2 and 3 wherein the polynucleotides of SEQ ID NO 2 and 3 have three open reading frames (ORFs) of 524 (SEQ ID NO 4), 1194 (SEQ ID NO 5), and 656 amino acids each (SEQ ID NO 6) (ii) an isolated polynucleotide disclosed in SEQ ID NO 9 which encodes the protein disclosed in SEQ ID NO 10, vector comprising the polynucleotides of (i) and (ii), does not reasonably provide enablement for any other claimed embodiments for reasons of record set forth in the office action of 3-28-02. (Office Action at 3)

In addition, the action states that:

***[T]hese arguments do not address the issues such as: whether the sequences disclosed in SEQ ID NO 1 is a smaller fragment of the polynucleotide disclosed in SEQ ID NO 3 or 2 whether it is an independent sequence; whether the polypeptides encoded by SEQ ID NO 1 and by 2 and 3 are same and/or how related they are; whether the polypeptides encoded by SEQ ID NO 1 ORF, 924 and 218 amino acids in length would have the activity of Env proteins encoded by SEQ ID NO 2 and 3. (Office Action at 3-4)

The Rejection is respectfully traversed.

Applicants respectfully disagree with the rejection, however, in an effort to expedite prosecution of the application, claim 43 has been amended. The claim amendments are believed to obviate the rejection.

Applicants respectfully submit that to satisfy the enablement requirement the specification must contain "sufficient information regarding the subject matter of the claims as to enable one skilled in the art to make and use the claimed invention." (MPEP §2164.01). Furthermore, "[t]he test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (United States v. Teletronics, Inc., 8 USPQ2d 1217, 1223 (Fed. Cir. 1988); MPEP §2164).

Applicants further wish to point out that the current embodiments of the claims are directed to polynucleotide fragments having nucleotides 5620 to 7590 of SEQ ID NO: 3 and sequences having at least 95% sequence identity over their entire length to the sequence between nucleotides 5620 to 7590 of SEQ ID NO: 3, wherein the polynucleotides encode an ENV polypeptide. The specification clearly provides sufficient guidance to enable one skilled in the art to make and use the currently claimed embodiments. For example, as discussed above, the specification provides the complete coding region for the ENV polypeptide (comprising nucleotides 5620 to 7590 of SEQ ID NO: 3) and a modified version of the ENV gene isolated from RAJI cells infected with PoEV (SEQ ID NO: 9). The specification also provides a number of working examples supporting the claimed invention. For example, Examples 1 to 4 (at pages 19-23) describe the cloning and sequencing of viral DNA sequences, including the sequence encoding the ENV polypeptide from PoEV. Example 9 (at pages 30-34) describes the amplification and analysis of PoEV sequences from PoEV infected RAJI cells, including analysis of the env gene from PoEV. The Specification also teaches that nucleotide sequences having at least 95% sequence identity to SEQ ID NO: 3 may be isolated by their ability to hybridize with these sequences (see e.g., pages 7-8).

With respect to SEQ ID NOs: 1, 2, and 3 and how they relate to one another, Applicants respectfully point out that these sequences are clearly described at pages 22-23 of the specification. Furthermore, since the current embodiment of the claims are directed to sequences

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comprising a portion of SEQ ID NO: 3 or sequences having 95% identity thereto wherein the sequences encode an ENV polypeptide, Applicants are not clear as to how the relationship between SEQ ID NOS: 1, 2, and 3 bears on the enablement of the claimed embodiment.

Accordingly, the specification clearly provides sufficient guidance, working examples, and evidence as to how an artisan would have made and used the claimed invention without undue experimentation. In view thereof, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 43-47 and 49-64 Rejected under 35 U.S.C. §102(e)

Claims 43-47 and 49-64 were rejected under 35 U.S.C. §102(e) as being anticipated by Fishman et al. US Patent No. 6,190,861 for reasons of record set forth in the office action of March 28, 2002. The current action states that:

It is noted that claim 43b does not recite that the sequence has the recited identity over the entire sequence of the claimed sequence. Therefore, any parts of the sequence of Fishman et al that have sequence identity with parts of the claimed sequence will anticipate the claimed nucleic acid. Same will be true for claim 43c and claim 49.

The rejection is respectfully traversed.

Applicants respectfully disagree with the rejection, however, in an effort to expedite prosecution of the application, claim 43 has been amended as suggested by the Examiner. The claim amendments are believed to obviate the rejection. In view thereof, reconsideration and withdrawal of the rejections are respectfully requested.

CONCLUSION

Applicants consider the Response herein to be fully responsive to the referenced Office Action. Based on the above Remarks, it is respectfully submitted that this application is in condition for allowance. Accordingly, allowance is requested. If a telephone conversation with Applicant's Agent would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1000.

Respectfully submitted,

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Marked-up version of the amendments to the claims:

Please amend claims 43 and 46 as set forth below:

43. (Amended) An isolated polynucleotide fragment comprising:

- (a) a nucleotide sequence having nucleotides 5620 to 7590 of SEQ ID NO: 3;
- (b) a nucleotide sequence which has at least 95% sequence [75%] identity over its entire length to the sequence set forth in (a); or
- (c) a nucleotide sequence which is complementary to a nucleotide sequence set forth in (a) or (b);

and wherein (a), (b) or (c) encodes an ENV polypeptide.

49. (Amended) An isolated polynucleotide fragment comprising a nucleotide sequence [which has at least 90% identity to a sequence having] having nucleotides 5620 to 7590 of SEQ ID NO: 3, or a nucleotide sequence which is complementary thereto.